

Unclassified

DAF/COMP/GF/WD(2014)31

Organisation de Coopération et de Développement Économiques  
Organisation for Economic Co-operation and Development

28-Jan-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE

## Global Forum on Competition

### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from Chinese Taipei

-- Session III --

*This contribution is submitted by Chinese Taipei under Session III of the Global Forum on Competition to be held on 27-28 February 2014.*

Ms Cristiana Vitale, Senior Competition Expert, OECD Competition Division  
Tel: +33 1 45 24 85 30, Email: cristiana.vitale@oecd.org

JT03351574

Complete document available on OLIS in its original format

*This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.*



DAF/COMP/GF/WD(2014)31  
Unclassified

English - Or. English

## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

### -- Chinese Taipei --

1. This paper will outline the pharmaceutical market and the drug pricing system under the National Health Insurance (NHI) in Chinese Taipei, and address the competition issues and cases in pharmaceutical industry that have been investigated by the Fair Trade Commission (FTC). In preparing this paper, the FTC consulted the central health competent authority, the Ministry of Health and Welfare, to provide relevant information.

#### 1. Chinese Taipei's Pharmaceutical Industry

2. In accordance with Article 6 of Chinese Taipei's "Pharmaceutical Affairs Act," the term "Pharmaceuticals" refers to the following "active pharmaceutical ingredients (API)" and "preparations": (1) drugs which are listed in the Chinese Pharmacopoeia, or in the Pharmacopoeia of other countries, the official National Formularies or any of their supplements recognized by the central health authority; (2) drugs which are not included in the preceding Sub-paragraph but are used in diagnosing, curing, alleviating or preventing the diseases of human beings; (3) other drugs which are sufficient to affect the body structure and physiological functions of human beings; (4) drugs which are used in preparing such drugs set forth in the preceding three sub-paragraphs. "Pharmaceuticals" can thus be divided into API (including pharmaceutical intermediates) and preparations. Preparations are processed and compounded from raw materials into a specific pharmaceutical form and dosage for easy taking, and consist of both Western medicines and Chinese medicines. The Ministry of Health and Welfare has classified pharmaceutical preparations into four categories according to safety and efficacy: (1) medicines prescribed by physicians; (2) medicines designated by physicians, pharmacists or assistant pharmacists; (3) over-the-counter medicines, which are mild and have a broader safety scope, and thus can be purchased without prescription from physicians; and (4) preparations of inherited formula, namely, Chinese medicines. Thus, pharmaceutical industry in Chinese Taipei includes API, Western medicine and Chinese medicine preparations, and other relevant products.

3. The value of total output of pharmaceutical manufacturing in Chinese Taipei in 2012 was NT\$69.6 billion dollars (about US\$2.32 billion dollars) with a large contribution coming from API products and Western medicine preparations<sup>1</sup>. The value of imports was NT\$73.91 billion dollars (about US\$2.464 billion dollars), of which Western medicine preparations accounted for 92%. Domestic pharmaceutical manufacturers provided 61% of volume in the market, but only made up about 23.2%<sup>2</sup> in terms of total sales income. The major reason, taking preparations as an example, is that most domestic pharmaceutical manufacturers are small to medium-sized companies that lack the capability to develop new drugs, and hence mainly produce generic drugs so that new drugs or patented drugs are largely imported.

---

<sup>1</sup> Department of Industrial Technology, Ministry of Economic Affairs: "2013 Yearbook of Pharmaceutical Industry", p3.

<sup>2</sup> *Ibid*, p.54.

4. There are two marketing channels for pharmaceuticals in Chinese Taipei, namely, API products and preparations. The API and preparations products produced in other countries are sold by their commercial agents to compete with domestic pharmaceutical manufacturers who purchase domestically-made pharmaceutical raw materials or else import raw materials to produce API products. Finished API products and preparations are sold to hospitals, clinics and pharmacies and then to consumers. Such sales channels are one way and straightforward. Hospitals are the largest customers in the market, and account for about 50% of sales. Furthermore, since the procurement of medicines by public hospitals requires that certain tender procedures be followed, as to whether or not the “procurement price” is reasonably in line with the NHI “medicine payment” claimed by hospitals has become the focus a public opinion.

## **2. Regulations on the distribution of pharmaceuticals**

5. As stipulated in Articles 14 and 15 of the Pharmaceutical Affairs Act, “pharmaceutical firms” refer to dealers and manufacturers of drugs or medical devices that are engaged in wholesaling, retailing, importing and exporting pharmaceuticals. Any person with the intent to be a pharmaceutical firm is required to file an application to the municipal or county (city) health competent authority in order to receive approval and registration. The applicant is only permitted to start operation after paying the license fee and obtaining a business license. Pharmacies selling medicine are subject to the same regulations applied to pharmaceutical firms as they are engaged in the retailing of drugs of a certain level, in accordance with Paragraph 2 of Article 34 of the same Act. In addition, as stipulated in the Pharmacist Act, pharmacists shall be responsible for the sale or management of pharmaceuticals, and have to ensure that customers understand the directions and warnings related to any medicine they purchase. It is inappropriate to sell medicine through channels other than bricks and mortar stores, as it would not be possible to ensure that the people’s interests and rights in taking medicine were protected. To protect public health, pharmaceuticals, unlike other merchandise, are prohibited from distribution through the Internet, mail order or TV shopping in Chinese Taipei.

## **3. NHI Pharmaceutical pricing system**

6. The National Health Insurance (NHI) implemented in Chinese Taipei in 1995 is a single-payer compulsory social insurance plan. Medical services covered by the NHI include outpatient clinics, hospitalization, drugs and laboratory testing. The scope of drugs payment is very wide, ranging from domestically and internationally manufactured pharmaceuticals to imported pharmaceuticals for a total of at least 17,000 Western medicines preparations. There are no regulations that apply to pharmaceutical ex-factory prices in Chinese Taipei, but there are regulations regarding NHI payments and prices for medicines covered by the NHI in accordance with the “National Health Insurance Drug Payment Particulars and Regulations”.

7. On the structure of pharmaceutical distribution, large hospitals are the major marketing target. The NHI intended to make sure medical resources were used efficiently by attracting patients with minor ailments to clinics with a referral system and higher deductions. Unfortunately, the referral system has not succeeded so that large hospitals still hold most of the medical resources. Medicines produced by domestic pharmaceutical manufacturers account for only one third of the total medicine used by large hospitals, but medicines produced by/imported from international pharmaceutical firms account for a larger proportion. In other words, clinics and pharmacies are the marketing target of domestic pharmaceutical manufacturers.

8. As the NHI expenditure on pharmaceuticals has been increasing, the Ministry of Health and Welfare and the National Health Insurance Administration (NHIA) have been holding meetings with medical care institutions to discuss and amend the NHI pharmaceutical pricing regulations. An agreement was reached on September 17, 1996 to draft the “Principles of the National Health Insurance Drug Pricing System”, which took effect on November 1, 1996. One controversial point concerning these principles was

that the NHIA took international pharmaceutical price information as a reference for setting the price paid to the original drug manufacturers. The NHI pays the same price and forces drug manufacturers to adopt a unified payment for most drugs, with only a few essential drugs being paid up to the highest limit. The Ministry of Health and Welfare announced the “Guidelines for the National Health Insurance Drug List and Payment Schemes” on March 30, 1999 that showed the list of NHI pharmaceutical products and the prices that would be paid. The announcement was intended to disclose the content and claims procedures regarding which pharmaceuticals were covered by the NHI, as well as their pricing and payment.

#### **4. Controversial “drug pricing black hole”**

9. The term, “drug pricing black hole”, is an expression with a negative connotation used to describe the drug price gap in the NHI system. It indicates that the government pays medical care institutions higher prices for drugs than the actual price agreed upon procurement.

10. In the report of the NHIA regarding solving the problem of the NHI drug price gap, the gap was divided into two types, rational and irrational:

##### **4.1 Rational price gap**

###### *4.1.1 Clinics*

11. Clinics or primary-level NHI medical care institutions use a simple form for claiming a pharmaceutical payment of NT\$75 every 3 days, but the average pharmaceutical price every 3 days is only NT\$50, resulting in a difference of about NT\$25.

###### *4.1.2 Hospitals*

12. Public and private hospitals, regardless of whether they are large or small, may obtain discounts from pharmaceutical firms according to the amount of pharmaceuticals purchased, the delivery location, and pay out conditions. The discounts vary from 15% to 30%.

##### **4.2 Irrational pricing difference**

###### *4.2.1 High discount rates, or gifts*

13. Private general hospitals may obtain higher discounts or receive high value gifts for drugs whose patents have expired but where the price remains the same, but still claim the NHI payment at the same price on the drug list. This is the main cause of the “drug pricing black hole”.

###### *4.2.2 Claiming the payment for “drug B” with the price of “drug A”*

14. Some NHI medical care institutions purchase and use drug A at a lower price, but claim the NHI payment for a more expensive drug B. Fines and punishments are stipulated in Paragraph 3 of Article 4 of the “Regulations of National Health Insurance Drug Payment Price Adjustment” against fraudulent claims or non-claims for NHI payment. Such cases were found in the early stages after the implementation of the NHI, but are now rarely seen.

15. In September 1999, the FTC investigated whether the drug price gap violated the regulations of the Fair Trade Act (FTA). The investigation involved meetings with the health authority, pharmaceutical manufacturers and medical care experts before the drafting of the “Guidelines for the Disclosure of Procurement Information at Medical Care Institutions (Draft)”. The FTC attempted to help the NHIA obtain the actual trading price in the market as a reference for lowering the threshold of the drug price.

However, it was concluded that the issue of the drug price gap relied on the cooperation between various institutions so that it could not be solved solely by the administrative regulations stipulated in the aforementioned draft proposed the FTC. Moreover, the trading information between three parties, the buyer (medical care sector), the seller (pharmaceutical firms) and the NHIA, to some extent is available to each of them. It is unlike those cases where the FTC found asymmetric information between trading parties. Therefore, the FTC decided to suspend the finalization of the guidelines.

## **5. Competition among generic drugs**

16. According to the statistics for pharmaceutical permits in 2012, permits for generic drugs in Chinese Taipei accounted for 82.4%, out of which permits for domestically made generic drugs made up 89.6% and those for imported ones the remaining 10.4%. As revealed by data in past years, about 70% of NHI drugs were domestically made generic drugs. Pharmaceutical supply in Chinese Taipei relies mainly on domestic pharmaceutical manufacturers. There are no trading and import barriers, or restrictions on the acquisition of generic drugs, and competition among generic drugs is intense.

17. When the patents of patented drugs expire, the patent holding pharmaceutical manufacturers are forced to lower their prices and face competition from generic drugs. This fact applies to all pharmaceutical manufacturers around the world. In order to rationally control expenditure on medicine, unless the expired patented drugs are marked as irreplaceable, pharmacists can replace them with substitutes, which are less expensive or made by other pharmaceutical manufacturers but contain the same active ingredients (including generic drugs). Physicians are allowed to prescribe appropriate medicine based on the patient's condition, and there are no restrictions on the use of generic drugs or the highest daily limit of pharmaceutical expenditure. The NHI pharmaceuticals and amounts of NHI payments are disclosed on the NHIA website. The NHIA does not offer any financial incentives to physicians, pharmacists or consumers regarding prescribing or using generic drugs. To avoid unnecessary waste and the irrational use of generic drugs, the NHIA reviews pharmaceutical expenditure carefully. Medical records have been integrated by cloud computing technology, and are provided as a reference to physicians for prescribing generic drugs. All these measures have been intended to improve the quality of medical care and ensure resources are used rationally.

18. In Chinese Taipei, pharmaceuticals should go through the process of Drug Review and Registration, and can only be manufactured, imported or distributed after being granted a permit. The review process emphasizes safety, efficacy and quality: the safety review includes a discussion of pharmaceutical toxicity and adverse effects; the efficacy review involves the evaluation of the therapeutic effect; and the quality review seeks sustainable and stable manufacturing and management. Generic drugs should be consistent with the original patented drugs in terms of ingredients, drug form, therapeutic effect and dosage. They should be considered as the formula and product, to which modifications are made for developing new drugs. Hence, documents regarding their safety and efficacy are not required while applying for Drug Review and Registration. With respect to quality, applicants are required to submit the standard operational handbook for chemical manufacturing and control (the content should include controls over the physical and chemical properties of raw materials, testing specifications and methods, manufacturing processes and stability tests, etc.). A common practice in many countries is that, for generic drugs, it is not necessary to repeat all the clinical trials regarding the safety and efficacy of their active ingredients. According to international regulations, after development and production generic drugs are subject to bioequivalence tests by taking the original patented drugs as the standard control. The generic drugs and standard control are administered to the same group of subjects under the same conditions. The results should show no statistically significant differences between generic drugs and the standard control in terms of pharmacological effects or the amount and speed of active ingredients in blood circulation or on the functioning site. The results serve as a major reference for proving the safety and efficacy of generic drugs. Such a procedure is considered adequate for clarifying consumers' concerns about generic drugs.

19. There are no regulations in favor of the distribution and use of generic drugs in Chinese Taipei, but the differences in the prices of generic drugs and their original patented drugs are disclosed on the NHIA website.

**6. Case example: Hoan Pharmaceuticals violated the FTA by selling its product at a price under its cost for driving competitors out of the market**

20. The East Bamboo Co., Ltd. (hereafter referred to as the EB Company) was the sole sales agent of 10mg Epram Tablets whereas Hoan pharmaceuticals (hereafter referred to as the H company) was the sole sales agent of 10mg Lexapro® film-coated tablets. Containing the same active ingredient, Escitalopram, these two drugs were both used for treating depression, and thus these two companies were competitors. In September 2008, they both tendered for the supply of pharmaceuticals to the private Kaohsiung Medical University Chung-Ho Memorial Hospital (hereafter referred to as Chung-Ho Hospital). The EB Company complained to the FTC that they suspected the H Company offering depression drugs at a price below cost.

21. As revealed by the FTC's investigation, 10mg Lexapro® film-coated tablets, which had solely been distributed by the H Company in Chinese Taipei since 2005, constituted the original patented drug for depression with Escitalopram as an active ingredient. The 10mg Epram Tablets solely distributed by the EB Company since 2008 constituted the first generic drug sharing the same active ingredient as Lexapro® film-coated tablets. Before the introduction of the generic drug to the market, the H Company had already begun to sell Lexapro® in 2005, and up to 2007, achieved a sales volume of 123,038 packs (each pack contained 28 tablets for a total of 3,440,000 tablets) to 186 trading counterparts. By that time, the H Company had already established a strong marketing relationship with various large hospitals, clinics, pharmacists and shipping companies.

22. To offer tender for the supply of drugs to various medical centers, regional hospitals and large local hospitals, it is usually required that companies provide a document to prove that their drugs have been used by other medical centers. That is, if a company's tender has been accepted by one medical center, the company will have more chances of supplying drugs to other medical centers, regional hospitals and large local hospitals. It can be seen as the threshold for achieving a higher pharmaceutical sales volume. If the EB Company's tender was accepted by Chung-Ho Hospital on September 16, 2008, it could have offered tenders to other hospitals. This might have resulted in intense price competition for the H Company.

23. Both 10mg Lexapro® film-coated tablets and Epram Tablets were paid for by the NHI at the price of NT\$34.4 per tablet and NT\$27.5 per tablet, respectively. Although they contained the same ingredients, the former were manufactured by the patent holder and so the NHI payment price was NT\$6.9 higher than that of the latter. Medical care institutions could obtain more profit with a higher pharmaceutical price gap (i.e. the NHI payment price is higher than the purchase cost). Even if the EB Company were to offer some free pharmaceuticals (the maximum pharmaceutical price gap that medical care institutions can have is NT\$27.5), as long as the H Company were to sell the drug at a price that was NT\$6.9 lower, medical care institutions could profit from the NT\$27.5 price gap. Therefore, no rational economic reasons were found to explain why the H Company offered the tender for the supply of the drug at only NT\$1 to Chung-Ho Hospital.

24. The H Company's tender for the supply of the drug at a price much lower than the purchase cost in 2008 excluded the EB Company from offering tenders to other large hospitals. From 2008 to November 2010, the EB Company was excluded from offering tenders to most large hospitals and its Epram Tablets could only be sold to small hospitals and clinics. According to statistics compiled by the NHIA on the sales of these two drugs, from 2008 to 2010, 10mg Epram Tablets among all Escitalopram-based drugs accounted for shares of 1.61%, 4.89% and 5.36% of the market, respectively. Furthermore, on October 1,

2009, the NHI payment price for 10mg Epram Tablets was lowered from NT\$27.5 to NT\$25.6 and the sales revenue was significantly affected while the EB Company was able to enter the market of the NHI covered drugs.

25. The FTC concluded that the H Company, which offered a tender for the supply of Lexapro® at a price much lower than its purchase cost, i.e., at a price of NT\$1, and excluded other companies from fair competition, violated the regulations stipulated in Paragraph 3 of Article 19 of the FTA. The H Company was ordered to cease the behavior described above and was subjected to a penalty of NT\$3,000,000. However, this case was revoked by the Taipei Higher Administrative Court. One of the reasons given was that the FTC made such judgment only based on the price that the NHI paid for these two drugs without taking into account the actual trading price, discount, gifts and quantity among all medical care institutions while comparing their sales volumes and costs. The Court is of the view that the FTC erroneously determined that there lacked rational economic reasons for such deals only by observing an individual transaction. The FTC subsequently appealed this case to the Supreme Administrative Court. The case has returned to the Taipei Administrative Court again as its ruling was revoked by the Supreme Administrative Court.